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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,121	05/23/2006	Marian Thomas	PB60383USw	5278

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EXAMINER	
KUDLA, JOSEPH S	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
06/13/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/564,121	THOMAS, MARIAN	
	Examiner	Art Unit	
	JOSEPH S. KUDLA	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16 and 18-28* is/are pending in the application.

4a) Of the above claim(s) *11-14,16,18-23 and 25-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restriction

1. Applicant's March 24, 2008 correspondence elects Group III and the species 3-(4-{[6-({(2R)-2-hydroxy-2-[4-hydroxy-3- (hydroxymethyl)phenyl]ethyl}amino)hexyl]oxy}-butyl)benzene sulfonamide, without traverse, which encompasses instant claims 15 and 24. The invention contained in groups I, II, IV and V, encompassing instant claims 1-14, 16, 18-23 and 25-28, are withdrawn from consideration as being drawn to non-elected subject matter see 37 CFR 1.142(b). Accordingly, the subject matter now under consideration is drawn to claims 15 and 24.

Upon examination of the elected species, the Examiner has expanded the designation of "active ingredient substance."

The restriction having been made without traverse is herein made FINAL.

Priority

2. This application claims priority of International Patent Application Number PCT/EP2004/007669, filed on July 8, 2004; which claims priority from 0316338.3, filed on July 11, 2003, in the United Kingdom; US Provisional Application Number 60/505,390, filed on September 23, 2003; and 0324912.5, filed on October 24, 2003, in the United Kingdom.

Priority is acknowledged.

Information Disclosure Statement

3. The Information Disclosure Statement (IDS) correspondences submitted by Applicant on April 25, 2006 are acknowledged. The references have been reviewed to the extent each is a proper citation on a U.S. Patent.

4. The Information Disclosure Statement filed February 17, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, the document with citation number 38 by Zeng et al. has not been provided.

Appropriate action is required.

5. Applicant should be aware that the examiner has limited time to spend per case and the references provided in the IDS were afforded all of the consideration such time constraints allow. In the interest of reducing the examination burden on the Office, applicant should consider providing page and paragraph notations as to where pertinent information may be found in the references listed on the IDS forms.

Title

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Almarsson et al. (US Patent US 6,559,293), in view of all Staniforth et al. (WO 2001/078694 and cited by Applicant), Muller-Walz et al. (WO 02/078671 and cited by Applicant (citations from English language equivalent of US Non-provisional Application 10/473874 and provided to Applicant)) and Keller et al. (WO 00/28979 and cited by Applicant (citations from English language equivalent of US Patent 6,645,466)).

The instant claims are drawn to a method of inhibiting chemical degradation of primary and secondary amine containing active ingredients with a formulation that contains as a carrier lactose and calcium stearate.

Almarsson et al. teach that "The suitability of a particular excipient may also depend on the specific active ingredients in the dosage form. For example, the decomposition of some active ingredients can be accelerated by some excipients such

as lactose, or when exposed to water. Actives ingredients that comprise primary and secondary amines are particularly susceptible to such accelerated decomposition" (column 17, lines 15-21).

Almarsson et al. does not teach a method of formulation where the addition of calcium stearate can inhibit the chemical degradation of a primary and secondary amine containing active ingredient.

Staniforth et al. teach a secondary amine containing active ingredient (i.e., formoterol) that is used in a formulation with magnesium stearate and lactose (page 43, lines 16-19) for an inhalation device (reference claim 1). Staniforth et al. teaches the carrier is lactose (reference claim 4) and the additive material includes salts of stearic acid (page 17, lines 16-23) and specifically calcium stearate (page 35, line 30 and page 40, Table 4). Staniforth et al. teach that the additive material limits the interaction of the active ingredient and the carrier molecule by occupying all of the high energy sites on the carrier particle allowing for easier release of the active from the carrier in the lungs (page 13, lines 12-21).

Muller-Walz et al. teach a medical suspension aerosol formulation and to the use of certain salts as excipients in such formulation (page 1, lines 3-5). Muller-Walz et al. teach the salt is a carboxylic acid salt, such as calcium stearate (page 6, lines 32-35) and has the ability to improve suspension stability and chemical stability (page 7, lines 4-10). The salts are found to improve chemical stability through improved moisture resistance (page 10, line 10-14).

Keller et al. teach the improvement of moisture resistance of dry powder formulations (column 1, lines 8-10) with magnesium stearate (column 4, lines 44-45). Keller et al. teach a dry powder formulation where lactose and magnesium stearate are mixed then combined with a secondary amine containing active ingredient (i.e., formoterol) (column 9, Example 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention that because it was known that compounds that comprise primary and secondary amines are particularly susceptible to such accelerated decomposition especially when brought into contact with some excipients such as lactose or when exposed to water as taught by Almarsson et al., any agent which *minimized interaction* between a primary and secondary amine containing compound formulated with lactose or provided *moisture resistance* would protect the primary and secondary amine containing compound from chemical degradation. One of ordinary skill in the art would have been apprised of Staniforth et al., Muller-Walz et al., Keller et al. and realized that the stearates (such as calcium and magnesium) would have provided protection against moisture and limited interaction between the lactose and active ingredient. Therefore, combining the references of Almarsson et al., in view of all Staniforth et al., Muller-Walz et al. and Keller et al. provides the *suggestion* that moisture exposure and chemical interaction needs to me minimized and *motivation* to utilize a stearate, such as calcium stearate, to do so, thus rendering instant claims 15 and 24 obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Application 10/564191

8. Claim 15 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent Application 10/564191 (Monteith et al.), in view of all Staniforth et al. (WO 2001/078694 and cited by Applicant) and Muller-Walz et al. (WO 02/078671 and cited by Applicant (citations from English language equivalent of US Non-provisional Application 10/473874 and provided to Applicant)). Although the conflicting claims are not identical, they are not patentably distinct from each other because Monteith et al. teach a method of inhibiting chemical degradation of an active substance in a formulation comprising a carrier, an active ingredient substance and a functional equivalent of the calcium stearate found in the instant invention.

Monteith et al. does not teach the use calcium stearate to aid in minimizing chemical degradation.

Staniforth et al. teach a secondary amine containing active ingredient (i.e., formoterol) that is used in a formulation with magnesium stearate and lactose (page 43, lines 16-19) for an inhalation device (reference claim 1). But Staniforth et al. also teaches the additive material can include salts of stearic acid (page 17, lines 16-23) and specifically calcium stearate (page 35, line 30 and page 40, Table 4). Staniforth et al. teach that the additive material limits the interaction of the active ingredient and the carrier molecule by occupying all of the high energy sites on the carrier particle allowing for easier release of the active from the carrier in the lungs (page 13, lines 12-21).

Muller-Walz et al. teach a medical suspension aerosol formulation and the use of certain salts as excipients in such formulation (page 1, lines 3-5). Muller-Walz et al. teach the salt is a carboxylic acid salt and includes such stearate salts such as magnesium and calcium stearate (page 6, lines 32-35). These salts have the ability to improve suspension stability and chemical stability (page 7, lines 4-10). The salts are found to improve chemical stability through improved moisture resistance (page 10, line 10-14).

It would have been obvious to one of ordinary skill in the art at the time of the invention that, in view of Staniforth et al. and Muller-Walz et al., the magnesium and calcium stearate salts are functional equivalents and an obvious variant of the instant invention unless unexpected results can be shown, therefore instant claim 15 is rendered obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph S. Kudla/
Examiner, Art Unit 1611
June 5, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615